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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,679	12/01/2003	Erning Xia	P03294	2369
23702 7590 09/12/2007 Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604-2701			EXAMINER ROGERS, JAMES WILLIAM	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			09/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/724,679	Applicant(s) XIA ET AL.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,6,10,12,15,19,24,25,30,31,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6,10,12,15,19,24-25,30-31 and 33-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/03/2007 has been entered.

Response to Amendment

Applicants amendment to the claims filed 08/03/2007 has been entered. Applicants have amended claims 1 and 10 and cancelled claims 7,17 and 26-29.

Response to Arguments

Applicant's arguments with respect to the claims rejected in the office action filed 05/18/2007 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,3,6,10,12,15,19,30-31 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howes (US 4,504,405, disclosed by applicants) in view of Ogunbiyi et al. (US 4,758,595, cited in previous office action).

Howes discloses methods of cleaning soft contact lenses using an aqueous solution containing an acceptable non-ionic surfactant such as poly(oxyethylene) stearate esters (commonly known as Myrjjs), poly(oxyethylene) ethers of C₈ to C₁₈ fatty alcohols (commonly known as Brijjs), sorbitan fatty acid esters (commonly known as Tweenjs), the preceding surfactants were described by applicants as having an HLB

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greater than 18 (see [0028] of applicants USPGPUB 2005/01181132) and polaxomers such as Pluronic L62 which is described by applicants as having an HLB less than 12 (see [0028] of applicants USPGPUB 2005/01181132). See abstract, col 1 lin 62-col 3 lin 32. Thus from the disclosure of Howes it would be obvious to combine two of the surfactants above in the same composition because the surfactants are employed in the same way and since they are listed together as surfactants combining two of the surfactants would have yielded predictable results to someone of ordinary skill in the art. Howes further discloses that the composition contains chlorhexidine salt which is a biguanidine and tonicity enhancing agents such as propylene glycol.

Howes while disclosing the use of biguanidines does not disclose the use the exact biguanidine agent polyhexamethylene biguanide eg PHMB or the antimicrobial polyquarternium 1 as presently claimed by applicants. Howes while disclosing that the solutions should have a pH value of from 5 to 8 is silent on the use of buffers to adjust the pH of the solution.

Ogunbiyi discloses solutions for disinfecting and/or preserving contact lenses, the solutions can comprise antimicrobials such as PHMB and surfactants such as Poloxamine 1107 described by applicants as having an HLB greater than 18 (see [0028] of applicants USPGPUB 2005/01181132). See col 2 lin 55-56, col 4 lin 4-25 and examples. Obunbiyi also discloses the use of buffers including citrate and phosphate buffers. See col 4 lin 57-lin 66. By combining Ogunbiyi with Howes it would have been obvious to one of ordinary skill in the art that the surfactant poloxamine 1107 could be combined with the surfactants disclosed within Howes because the surfactants are

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employed in the same way and since they are used for the same purpose combining two surfactants such as Polaxamine 1107 with Pluronic L62 would have yielded predictable results to someone of ordinary skill in the art.

It would have been prime facie obvious at the time of the invention to a person of ordinary skill in the art to modify the contact lens solution disclosed in Howes and add the buffers disclosed within Obunbiyi. It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. Also the active ingredient PHMB in applicants claimed contact lens solution would have been *prima facie* obvious from the combination of the two references above because the substitution of one known element such as biguanidine antimicrobials disclosed within Howes for another known element such as the antimicrobial PHBA disclosed within Obunbiyi would have yielded predictable results to one of ordinary skill in the art at the time of the invention. As shown by the recited teachings, instant claims are no more than the combination of conventional components of contact lens solutions. It therefore follows that the instant claims define prime facie obvious subject matter.

Claims 1,3,6,10,12,15,19,24-25,30-31 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howes (US 4,504,405, disclosed by applicants) in view of Ogunbiyi et al. (US 4,758,595, cited in previous office action) in view of Vehige et al. (US 5,858,346, cited in previous office action).

Howes and Obunbiyi are disclosed above and the reasons why they are obvious to combine is incorporated herein as well. Neither Howes or Obunbiyi disclose the use

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of polyquarternium 1 e.g. [4-tris(2-hydroxyethyl)ammonio]-2-butenyl-co-[tris(2-hydroxyethyl)ammonio] dichloride.

Vehige discloses solutions and methods for treating contact lenses, the solutions can comprise antimicrobials such as polyquarternium 1 and (PHMB). See abstract and col 6 lin 57-col 7 lin 12.

Thus by combining the art described above the claimed invention would have been *prima facie* obvious because the substitution of one known element such as the antimicrobials disclosed within Howes and Obunbiyi for another known element such as the antimicrobial polyquarternium 1 disclosed within Vehige would have yielded predictable results to one of ordinary skill in the art at the time of the invention. As shown by the recited teachings, instant claims are no more than the combination of conventional components of contact lens solutions. It therefore follows that the instant claims define prime facie obvious subject matter.

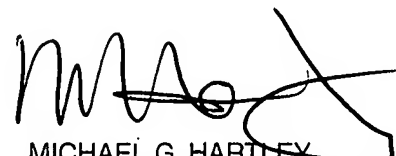
Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'MHartley', with a large, sweeping flourish extending from the end of the signature.

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (currently amended) Compositions for reducing the amount of lipid deposits on a contact lens comprising:

one or more nonionic polyether surfactants selected from the group consisting of poloxamer and poloxamine having a HLB value of less than 12;

a nonionic surfactant selected from the group consisting of poloxamer and poloxamine having HLB values of 18 or greater;

a wetting agent selected from the group consisting of poly(vinyl alcohol), propylene glycol and hydroxypropylmethyl cellulose; and

one or more antimicrobial agents selected from the group consisting of [4-tris(2-hydroxyethyl)ammonio]-2-butenyl- ω -[tris(2-hydroxyethyl)ammonio] dichloride and poly(hexamethylene biguanide).

Claim 2. (canceled)

3. (previously presented) The composition of claim 1, wherein the composition further comprises at least one member selected from the group consisting of a buffering agent, a chelating agent, and an osmolarity adjusting agent.

Claims 4 - 5. (canceled)

6. (previously presented) The composition of claim 3 wherein the buffering agent is selected from the group consisting of phosphate buffers and citrate buffers and mixtures thereof.

Claims 7. – 9. (canceled)

10. (currently amended) A method of cleaning and disinfecting a contact lens, the method comprising:

soaking a contact lens in an aqueous composition, wherein the composition comprises:

an effective amount of one or more nonionic polyether surfactants selected from the group consisting of poloxamer and poloxamine having a HLB value of less than 12 to reduce the amount of lipid deposits on said contact lens, and a nonionic surfactant selected from the group consisting of poloxamer and poloxamine having HLB values of 18 or greater;

a wetting agent selected from the group consisting of poly(vinyl alcohol), propylene glycol and hydroxypropylmethyl cellulose; and

one or more antimicrobial agents selected from the group consisting of [4-tris(2-hydroxyethyl)ammonio]-2-butenyl- ω -[tris(2-hydroxyethyl)ammonio] dichloride and poly(hexamethylene biguanide) to disinfect said contact lens.

Claim 11. (canceled)

12. (previously presented) The method of claim 10 wherein the composition further comprises at least one member selected from the group consisting of a buffering agent, a chelating agent, and an osmolarity adjusting agent.

Claims 13. – 14. (canceled)

15. (previously presented) The method of claim 10 wherein the composition further comprises a buffering agent selected from the group consisting of phosphate buffers and citrate buffers and mixtures thereof.

Claim 16. - 18. (canceled)

19. (previously presented) The method of claim 10 wherein the lipids are removed without manual rubbing said contacting lens.

Claims 20. – 23. (canceled)

24. (previously presented) The composition of claim 1, wherein the one or more antimicrobial agents includes [4-tris(2-hydroxyethyl)ammonio]-2-butenyl- ω -[tris(2-hydroxyethyl)ammonio] dichloride.

25. (previously presented) The method of claim 10, wherein the one or more antimicrobial agents includes [4-tris(2-hydroxyethyl)ammonio]-2-butenyl- ω -[tris(2-hydroxyethyl)ammonio] dichloride.

26. – 29. (canceled)

30. (currently amended) The composition of claim 1 wherein the ~~composition further~~ is propylene glycol.

31. (currently amended) The method of claim 10 wherein the ~~composition further~~ comprises is propylene glycol.

32. (canceled)

33. (previously presented) A composition for removing lipid deposits on a contact lens without rubbing the lens comprising:

a nonionic polyether surfactants selected from the group consisting of poloxamer and poloxamine having a HLB value of less than 12;

a nonionic surfactant selected from the group consisting of poloxamer and poloxamine having a HLB value of 18 or greater;

one or more antimicrobial agents selected from the group consisting of [4-tris(2-hydroxyethyl)ammonio]-2-butenyl- ω -[tris(2-hydroxyethyl)ammonio] dichloride and poly(hexamethylene biguanide); and
propylene glycol.

34. (previously presented) The composition of claim 33 wherein the composition further comprises buffering agents selected from the group consisting of phosphate buffers, citrate buffers and mixtures thereof.